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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2017-0663; FRL-9875-01-OCSPP]

5-Decyne-4,7-diol, 2,4,7,9-tetramethyl- and 6-Dodecyne-5,8-diol, 2,5,8,11-tetramethyl-; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of 5-decyne-4,7-diol, 2,4,7,9-tetramethyl- (CAS Reg. No. 126-86-3), herein referred to as TMDD, and 6-dodecyne-5,8-diol, 2,5,8,11-tetramethyl- (CAS Reg. No. 68227-33-8), herein referred to as TMDDD, when used as inert ingredients (surfactants, related adjuvant of surfactants and carriers) in pesticide formulations applied to growing crops pre- and post-harvest, and applied in/on animals. Spring Trading Company (new name Spring Regulatory Sciences) on behalf of Evonik Corp., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting the establishment of exemptions from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of TMDD and TMDDD**.**

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2017-0663, is available at *https://www.regulations.gov* or at the

Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566-1744. For the latest status information on EPA/DC services, docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echevarria, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (202) 566-1030; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Office of the Federal Register's e-CFR site at

https://www.ecfr.gov/current/title-40.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2017-0663 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2017-0663, by one of the following methods:

• *Federal eRulemaking Portal*: *https://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/contacts.html*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets*.

II. Petition for Exemption

In the *Federal Register* of March 12, 2018 (83 FR 12311) (FRL-9974-76), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-11077) by Spring Regulatory Sciences, 6620 Cypresswood Dr, Suite 250, Spring, TX 77379 on behalf of Evonik Corp., P.O. Box 34628, Richmond, VA 23234. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of TMDD (CAS Reg. No. 126-86-3) and TMDDD (CAS Reg. No. 68227-33-8) when used as inert ingredients (surfactants, related adjuvant of surfactants and carriers) in pesticide formulations applied to growing crops pre- and post-harvest and applied in/on animals under 40 CFR 180.930. That document referenced a summary of the petition prepared by Spring Regulatory Sciences on behalf of Evonik Corp., the petitioner, which is available in the docket via *https://www.regulations.gov.* There were no relevant comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity

of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA

section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for TMDD and TMDDD including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with TMDD and TMDDD follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by TMDD and TMDDD as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

TMDD and TMDDD are being assessed together because there is only a difference in carbon chain length between the two surfactants. Therefore, based on structure similarity, the toxicity profile is expected to be similar for TMDD and TMDDD.

Acute toxicity studies were available for both chemicals. TMDD exhibits moderate acute oral toxicity with the rat acute oral lethal dose (LD_{50}) being greater than 500 mg/kg. TMDDD exhibits low acute oral toxicity with the rat acute oral LD_{50} being greater than 5,000 mg/kg. Dermal toxicity is moderate in rabbits for both chemicals, as the LD_{50} is greater than 1,000 mg/kg, the highest dose tested. Acute toxicity via inhalation is low. Both have a lethal concentration (LC_{50}) > 20 mg/L. The chemicals are both highly irritating to the eyes and slightly irritating to the skin of rabbits. TMDD is not a skin sensitizer. The results for skin sensitization are equivocal for TMDDD.

Based on the available repeated-dose data on TMDD and TMDDD, the central

nervous system is a major target organ, with convulsions, tremors, paralysis and/or incoordination seen in dogs at 250 mg/kg/day following treatment for 91 days via capsule. The liver is also a target organ, with hepatocellular swelling observed in the one-generation reproduction toxicity study in rats but these effects were observed only at the limit dose (1,000 mg/kg/day). Additionally, non-specific effects (decreased body weights) were observed in offspring in the one-generation reproduction toxicity study, but these occurred at the same doses in which maternal toxicity was observed.

No mutagenicity, genotoxicity or chromosomal aberrations are seen in a battery of mutagenicity tests with TMDD and TMDDD. Both chemicals were negative in the Ames test, chromosome aberration test and mouse lymphoma assay.

Neurotoxicity studies are not available for review. Convulsions, tremors, paralysis and/or incoordination were observed at 250 mg/kg/day in dogs in a 91-day oral toxicity study via gavage. However, a clear NOAEL was established for these effects and the chronic population adjusted dose (cPAD) of 2 mg/kg/day is based on this study. Therefore, there is no concern for neurotoxicity.

Immunotoxicity toxicity studies are not available for review. However, no evidence of immunotoxicity is seen in the available studies.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern (LOCs) to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which NOAEL and the LOAEL Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level generally referred to as a population-adjusted

dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *https://www.epa.gov/pesticides/factsheets/riskassess.htm.*

No acute endpoint was identified; therefore, an acute assessment is not necessary. The 91-day oral study in dogs was selected for chronic dietary exposure as well as incidental oral, dermal and inhalation exposure scenarios. In this study, convulsions, tremors, paralysis and/or incoordination were observed at 250 mg/kg/day. This represents the lowest NOAEL in the database in the most sensitive species. The standard uncertainty factors (UFs) were applied to account for interspecies (10x) and intraspecies (10x) variations. The default value of 100% was used for the dermal and inhalation absorption factors.

C. Exposure Assessment

1. *Dietary exposure.* In evaluating dietary exposure to TMDD and TMDDD, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from TMDD and TMDDD in food as follows:

An acute dietary assessment was not performed due to the lack of adverse effects attributed to a single dietary exposure seen in the toxicity databases.

In conducting the chronic dietary exposure assessment using the Dietary Exposure Evaluation Model DEEM–FCIDTM, Version 4.02, EPA used food consumption information from the U.S. Department of Agriculture's (USDA's) 2005-2010 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, no residue data were submitted for TMDD and TMDDD. In the absence of specific residue data, EPA has developed an

approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high use insecticides, herbicides, and fungicides. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled ''Update to D361707: Dietary Exposure and Risk Assessments for the Inerts.'' (12/21/2021) and can be found at *https://www.regulations.gov* in docket ID number EPA-HQ-OPP-2018-0090.

In the dietary exposure assessment, the Agency assumed that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation (if any) between the active and inert ingredient and that the concentration of inert ingredient in the scenarios leading to these highest levels of tolerances would be no higher than the concentration of the active ingredient.

The Agency believes the assumptions used to estimate dietary exposures lead to an extremely conservative assessment of dietary risk due to a series of compounded conservatisms.

First, assuming that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient will overstate exposure. The concentrations of active ingredient in agricultural products are generally at least 50 percent of the product and often can be much higher. Further, pesticide products rarely have a single inert ingredient; rather there is generally a combination of different inert ingredients used which additionally reduces the concentration of any single inert ingredient in the pesticide product in relation to that of the active ingredient.

Second, the conservatism of this methodology is compounded by EPA's decision to assume that, for each commodity, the active ingredient which will serve as a guide to

the potential level of inert ingredient residues is the active ingredient with the highest tolerance level. This assumption overstates residue values because it would be highly unlikely, given the high number of inert ingredients, that a single inert ingredient or class of ingredients would be present at the level of the active ingredient in the highest tolerance for every commodity.

Finally, a third compounding conservatism is EPA's assumption that all foods contain the inert ingredient at the highest tolerance level. In other words, EPA assumed 100 percent of all foods are treated with the inert ingredient at the rate and manner necessary to produce the highest residue legally possible for an active ingredient. In summary, EPA chose a very conservative method for estimating what level of inert residue could be on food, then used this methodology to choose the highest possible residue that could be found on food and assumed that all food contained this residue. No consideration was given to potential degradation between harvest and consumption even though monitoring data shows that tolerance level residues are typically one to two orders of magnitude higher than actual residues in food when distributed in commerce.

Accordingly, although sufficient information to quantify actual residue levels in food is not available, the compounding of these conservative assumptions will lead to a significant exaggeration of actual exposures. EPA does not believe that this approach underestimates exposure in the absence of residue data.

For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for TMDD and TMDDD, a conservative drinking water concentration value of 100 parts per billion (ppb) based on screening level modeling was used to assess the contribution to drinking water for chronic dietary risk assessments for TMDD and TMDDD. The exposure for food and water utilized 14.2% and 51.5% of the cPAD (2.00 mg/kg/day) for the U.S. population and children 1 to 2 years old, respectively.

2. Residential exposure. The term ‘‘residential exposure’’ is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). TMDD and TMDDD may be used as inert ingredients in pesticide products that are registered for specific uses that may result in residential exposure. A conservative residential exposure and risk assessments were completed for pesticide products containing TMDD and TMDDD as inert ingredients. The Agency assessed pesticide products containing TMDD and TMDDD using exposure scenarios used by OPP to represent conservative residential handler exposure. Further details of this residential exposure and risk analysis can be found at *https://www.regulations.gov* in the memorandum entitled: ‘‘JITF Inert Ingredients. Residential and Occupational Exposure Assessment Algorithms and Assumptions Appendix for the Human Health Risk Assessments to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations,’’ (D364751, 5/7/09, Lloyd/LaMay in docket ID number EPA-HQ-OPP-2008-0710).

For residential handler short-term exposure scenarios, MOEs ranged from 230 to 33,000 and are not of concern (i.e., MOEs are >100). Residential handler intermediate-term and long-term exposures are not expected because applications are not expected to occur daily or for more than 30 days. For residential post-application exposure scenarios (short- and intermediate-term), MOEs ranged from 510 to 13,000,000 and are not of concern (i.e., MOEs are >100).

3. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to TMDD and TMDDD and any other substances because TMDD and TMDDD do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance exemption, therefore, EPA has assumed that TMDD and TMDDD do not have a common mechanism of toxicity with other substances.

For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *https://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

In general. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

The Agency has concluded that there is reliable data to determine that infants and children will be safe if the FQPA SF of 10x is reduced to 1X for all exposure scenarios for the following reasons. The toxicity database for TMDD and TMDDD contain a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test, a one-generation reproduction toxicity and mutagenicity studies. No fetal susceptibility is observed in either the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test or in the 1-generation reproduction

toxicity study in rats. Offspring toxicity (decreased body weights at weaning and lactation) is seen in the one-generation reproduction toxicity study only at the same dose as maternal toxicity (hepatocellular swelling), 1,000 mg/kg/day. No reproduction toxicity is seen in the available studies. Convulsions, tremors, paralysis and/or incoordination were observed at 250 mg/kg/day in dogs in a 91-day oral toxicity study. However, a clear NOAEL was established for these effects and the selected POD is based on this study. Therefore, there is no concern for neurotoxicity. Based on the adequacy of the toxicity database, the conservative nature of the exposure assessment and the lack of concern for prenatal and postnatal sensitivity, the Agency has concluded that there is reliable data to determine that infants and children will be safe if the FQPA SF of 10X is reduced to 1X.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk*. An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, TMDD and TMDDD are not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to TMDD and TMDDD from food and water will utilize 51.5% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure.

3. *Short-term risk*. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

TMDD and TMDDD are currently used as inert ingredients in pesticide products that are registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to TMDD and TMDDD.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 149 for adults. Adult residential exposure combines high end dermal and inhalation handler exposure from liquids/trigger sprayer/home garden with a high-end post application dermal exposure from contact with treated lawns. For children, the aggregate MOE is 141. Children's residential exposure includes total exposures associated with contact with treated lawns (dermal and hand-to-mouth exposures). Because EPA's level of concern for TMDD and TMDDD are MOEs below 100, the calculated MOEs are not of concern.

4. *Intermediate-term risk***.** Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

TMDD and TMDDD are currently used as inert ingredients in pesticide products that are registered for use**s** that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to TMDD and TMDDD.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in aggregate MOEs of 592 for adults. Adult residential

exposure includes high end post application dermal exposure from contact with treated lawns. For children the aggregate MOE is 170. Children's residential exposure includes total exposures associated with contact with treated lawns (dermal and hand-to-mouth exposures). Because EPA's level of concern for TMDD and TMDDD are MOEs below 100, the calculated MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population*. EPA has not identified any concerns for carcinogenicity relating to TMDD and TMDDD. TMDD and TMDDD are not expected to pose a cancer risk to humans; therefore, a cancer aggregate assessment was not conducted.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to TMDD and TMDDD residues.

V. Other Considerations

Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of TMDD and TMDDD in or on any food commodities.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 for residues of TMDD and TMDDD when used as inert ingredients (surfactants, related adjuvant of surfactants and carriers) in pesticide formulations applied in/on growing crops pre- and post-harvest and applied in/on animals under 40 CFR 180.930.

VII. Statutory and Executive Order Reviews

This action establishes exemptions from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of

Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemptions in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the National Government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal

Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Dated: June 9, 2022.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180--TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In §180.910, amend Table 1 to 180.910, by adding in alphabetical order, the entries for "5-decyne-4,7-diol, 2,4,7,9-tetramethyl- (CAS Reg. No. 126-86-3)" and "6-dodecyne-5,8-diol, 2,5,8,11-tetramethyl- (CAS Reg. No. 68227-33-8)" to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Table 1 to 180.910

Inert ingredients	Limits	Uses
* * * * * * *		
5-decyne-4,7-diol, 2,4,7,9-tetramethyl- (CAS Reg. No. 126-86-3)		surfactant, related adjuvant of surfactants and carriers
6-dodecyne-5,8-diol, 2,5,8,11-tetramethyl- (CAS Reg. No. 68227-33-8)		surfactant, related adjuvant of surfactants and carriers
* * * * * * *		

3. In §180.930, amend Table 1 to 180.930, by adding in alphabetical order, the entries for "5-decyne-4,7-diol, 2,4,7,9-tetramethyl- (CAS Reg. No. 126-86-3)" and "6-dodecyne-5,8-diol, 2,5,8,11-tetramethyl- (CAS Reg. No. 68227-33-8)" to read as follows:

§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.

* * * * *

Table 1 to 180.930

Inert ingredients	Limits	Uses
* * * * * * *		
5-decyne-4,7-diol, 2,4,7,9-tetramethyl- (CAS Reg. No. 126-86-3)		surfactant, related adjuvant of surfactants and carriers
6-dodecyne-5,8-diol, 2,5,8,11-tetramethyl- (CAS Reg. No. 68227-33-8)		surfactant, related adjuvant of surfactants and carriers
* * * * * * *		

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